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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WILDER, CYNTHIA B	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,747	SALCEDA ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-10 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-10 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1130104
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on July 30, 2004 is acknowledged and has been entered. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Previous Objections and Rejections

3. The objections to the specification have been withdrawn in view of Applicant's amendments. The claim rejection under 35 U.S.C. 101 and 35 U.S.C. 112 first paragraph directed to claims 1-5, 7-10 and 15 as lacking utility and enablement is maintained and discussed below. The claim rejection under 35 U.S.C. 112 first paragraph directed to claims 1-5, 7-10 and 15 as lacking enablement for deposit information is withdrawn in view of Applicant's amendment to the specification. The claim rejection under 112 first paragraph directed to claims 1-5, 7-10 and 15 as lacking adequate written description is withdrawn in view of Applicant's amendment to claim 1. The claim rejection under 35 U.S.C. 112 second paragraph directed to claims 1-5 as being indefinite is withdrawn in view of Applicant's amendment of claim 1. The claim rejection under 35 U.S.C. 112 second paragraph directed to claim 15 as being indefinite is withdrawn in view of Applicant's arguments. The prior rejection under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) directed to claims 1-5, 7-10 and 15 are withdrawn in view of Applicant's amendment of claim 1 and arguments.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Once again, the claims 1-5, 7-10 and 15 are rejected under 35 USC 101 because the claimed invention lacks patentable utility. The instant application does not disclose a specific, substantial, and credible utility for the nucleic acid sequence mentioned in the claims. The instant application does not disclose a connection between presence or expression of SEQ ID NO: 8 and ovarian cancer. For example, none of he tables between 114 and 127 shows such nexus. The demonstration of expression of a sequence in a specific tissue type cannot be translated to mean that that sequence is necessarily a marker for cancer in that tissue. In addition, the application does not disclose or teach the meaning or significance of any particular assay for expression of SEQ ID NO: 8. Thus, the instant application does not disclose a specific, substantial, and credible utility for SEQ ID 8, nor is there a readily apparent utility under 35 USC 1012 for SEQ ID NO: 8.

Claim Rejections - 35 USC § 112 first paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Once again, claims 1-5, 7-10 and 15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible or an asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make and/or use the claimed invention. The discussion in the rejection under 35 USC 101 is incorporated here.

Applicant's Traversal

8. Applicant's amendment and arguments filed on February 24, 2004 have been thoroughly reviewed and considered but are not found persuasive. Applicant traverses the rejections on the following grounds: Applicant summarizes the Examiner's rejection and asserts that "the rejections are based upon an improper characterization of the teachings of the instant specification". Applicant's state that "contrary to the Examiner's suggestion, the nexus between SEQ ID NO: 8 expression and ovarian cancer is taught in Example 1 of the specification wherein mRNA subtraction assays demonstrative of differential expression of the OSNAs (ovary specific nucleic acids) including SEQ ID NO: 8 in cancer tissue versus normal tissue is described". Applicant states that "in theses experiments OSNAs including SEQ ID NO: 8 were first examined for degree of specificity for the tissue of interest". Applicant further asserts that "mRNA subtraction assays exhibiting differential expression of he OSNAs in cancer samples as compared to normal tissues were then performed". Applicant asserts that " the high level of tissue specificity, plus differential mRNA expression in matching samples versus normal samples, in indicative of SEQ ID NO: 1 through SEQ ID NO: 76 being a diagnostic marker for cancer". Applicant states that "theses teaching of the specification make clear that identification of SEQ ID NO: 8 as a cancer marker is not based simply on tissue specificity, but also on mRNA differential expression in cancer samples". Applicant states that "case law on utility is quite clear; mere identification of a pharmacological activity on a claimed compound that is relevant to an asserted pharmacological use provides an immediate benefit to the public and thus satisfies the utility requirement (*Nelson V. Bowler*, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980))". Finally, Applicant concludes that "clearly identification of SDQ ID NO: 8 as having a high level

of tissue specificity, plus mRNA differential expression in cancer samples as compared to normal samples constitutes a pharmacological activity relevant to the asserted use as a diagnostic for ovarian cancer, thus satisfying the utility requirements of 35. U.S.C. 101 and 35 U.S.C. 112. Applicant respectfully request withdrawal of the rejections.

Examiner's Response

9. Applicant's amendment and arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow: In regards to Applicant's arguments that the specification clearly teaches the nexus between SEQ ID NO: 8 expression and ovarian cancer as taught in Example 1 wherein mRNA subtraction assay demonstrative of differential expression of the OSNAs including SEQ ID NO: 8 in cancer tissue versus normal tissues is described, it is noted that such teachings could not be found in Example 1 which begins at page 113 of the specification. The specification at Example 1 teaches "Gene Expression Analysis" and states in line 23, that "OSGs (ovary specific genes) were identified by mRNA subtraction analysis using standard methods". There is **no teaching** in the specification or Example 1, wherein OSNAs including SEQ ID NO: 8 were first examined for degree of specificity for the tissue of interest or wherein mRNA subtraction assays exhibiting differential expression of the OSNAs in cancer samples as compared to normal tissues were then performed. Thus, based on the limited teachings in the specification at Example 1, it would be difficult and impossible for one to arrive as such conclusions as argued above. Applicant is welcome to point out wherein Example 1 such teachings are found. As stated in the previous Office action, the specification does not disclose a connection between the presence of or expression of SEQ ID NO: 8 and

ovarian cancer. Likewise, none of the Examples 1 through 13 or Tables provides such nexus. Merely, making a statement in the specification of gene expression analysis does not equate to the identification of SEQ ID NO: 8 as a diagnostic marker for cancer. Applicant's arguments are not sufficient to overcome the rejections under 35 U.S.C. 101 and 35 U.S.C. 112 first paragraph. Accordingly, the rejections are maintained.

New Ground(s) of Rejections

THE NEW GROUND(S) OF REJECTIONS WERE NECESSITATED BY APPLICANT'S AMENDMENT TO THE CLAIMS:

Claim Rejections - 35 USC § 112: New Matter

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-5, 7-10 and 15 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn to an isolated nucleic acid molecule comprising (a) a nucleic acid molecule comprising a nucleic acid sequence that encodes an amino acid sequence of SEQ ID NO: 82; (b) a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 7 or 8; and (c) a nucleic acid molecule having at least 80% sequence identity to the nucleic acid molecule of (a) or (b) which is differentially expressed in ovarian cancer. Nowhere in the

specification is there a disclosure of "a nucleic acid molecule having at least 80% sequence identity to the nucleic acid molecule of (a) or (b) which is differentially expressed in ovarian cancer". Applicant provides no cited support for the new limitations of claim 1 and thus a review of the specification does not support or depict what is claimed. The specification teaches at paragraph 0017 that the nucleic acid molecules of the invention are specific to the ovary or to ovary cells or tissue that are derived from such nucleic acid molecule. At paragraph 0121, the specification teaches that the nucleic acid molecules exhibit substantial sequence similarity to a nucleic acid molecule encoding a polypeptide having an amino acid sequence of SEQ ID NO: 77 through 129. The specification teaches that the similar nucleic acid molecule is one that has at least 60% sequences identity with a nucleic acid molecule encoding an ovary specific polypeptide, such as a polypeptide having an amino acid sequence of SEQ ID NO: 77 through 129, more preferably at least 70%, even more preferably at least 80% and even more preferably at least 85%. The specification further teaches that in a more preferred embodiment, the similar nucleic acid molecule is one that has at least 90% sequence identity with a nucleic acid molecule -encoding an ovary-specific polypeptide, more preferably at least 95%, more preferably at least 97%, even more preferably at least 98%, and still more preferably at least 99%. None of the Examples or the Tables teach a nucleic acid molecule having at least 80% sequence identity to the nucleic acid molecule of (a) or (b) which is *differentially expressed in ovarian cancer.* Therefore, the specification would not have suggested to the skilled artisan that the Applicant was in possession of the claimed invention as of the filing date of the application.

Conclusion

12. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (703) 305-1680. After January 14, 2004, the examiner cam be reached at (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0196.

CYNTHIA WILDER
PATENT EXAMINER

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
10/7/04